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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,111	08/04/2000	Jan Carlsson	1614-0238P	2114

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/27/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/633,111

Applicant(s)

CARLSSON ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed on 9/23/2002 has been received. Claims 1-10 are pending.
2. The text of those US codes not found in this office action may be found in a previous office action.

Claim Rejections - 35 USC § 102

3. Claims 1-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pristoupil for reasons of record in the previous office action, paper no. 11.

Pristoupil discloses the general trends in the development of chromatographic and electrophoretic techniques, and specifically teaches the use of nitrocellulose membrane filters. Pristoupil teaches the use of nitrocellulose membrane having pore size ranging from about 0.01 μm to 10 μm in chromatography and electrophoresis separation of proteins and nucleic acids (pages 109-110). Pristoupil disclose a chamber for membrane chromatography where chromatography in aqueous solutions is performed in a horizontal position (page 112, figure 1). The samples are applied on the test strip and after separation, proteins and nucleic acids are visualized by either the sandwich techniques or dyes. Pristoupil discloses that nitrocellulose membranes impregnated with a suitable antigen can be used for the rapid detection, saturation or quantitative determination of specific antibodies in micro amounts of materials (page 119).

Pristoupil differs from the instant invention in failing to specifically state that the polymeric membrane is attached to a liquid-impervious backing. However, Pristoupil teaches the membrane is lay flat on a glass plates in a chromatography chamber; therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

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modify the polymeric membrane of Pristoupil by attaching it directly to the glass plates because it is well known in the art that such backing provides the advantage of increased handling strength for the membrane. Pristoupil is considered to make obvious the instant claims because steps f2a through f2c of claim 1 are seen to be optional.

Response to Arguments

4. Applicant's arguments filed 9/23/02 have been fully considered but they are not persuasive.

Applicant argues that the instant method requires full chromatographic separation ability, i.e. specific separation, with minimal non-specific adsorption. Applicant asserts that this is the exact opposite of the method taught by Pristoupil, which functions through non-specific adsorption. Applicant argues that the method Pristoupil does not result in a full separation of components based on some physical property, and that Pristoupil relies on the non-specific adsorption of proteins to nitrocellulose to separate the components of a sample into only two zones, adsorbed protein zone and a low molecular weight component zone.

These arguments have been fully considered but are not deemed to be persuasive.

Chromatography, according to Stedman's Medical dictionary, 26th Edition, is:

The separation of chemical substances and particles (originally plant pigments and other highly colored compounds) by differential movement through a two-phase system. The mixture of materials to be separated is percolated through a column or sheet of some suitable chosen absorbent (e.g. an ion-exchange materials); the substances least absorbed are least retarded and emerge the earliest; those more strongly absorbed emerge later.

Applicant's argument of specific chromatography is confusing since there appear to be nothing "specific" about the claimed method. The claims recite a chromatographic assay comprising the separation of at least two components in a sample and their detection after separation. Pristoupil teaches the exact same method where a sample comprising at least two components is separated on nitrocellulose paper by a chromatographic assay. Pristoupil teaches washing the nitrocellulose matrix to prevent non-specific adsorption such as the high adsorption of proteins (step 1b). Separated components are detected by appropriate staining (page 113, second full paragraph) or by immuno detection (page 118, part d). This is equivalent to step f1) of claim 1. The nitrocellulose taught by Pristoupil is treated to impart ion-exchange function (page 115, second full paragraph through page 116). This is equivalent to step a) of claim 1.

The argument that the washing step taught by Pristoupil, to remove additives from the membrane, teaches away from the instant step of treating the membrane, to prevent non-specific adsorption, has been fully considered but is not deemed to be persuasive. Pristoupil does not teach that the washing step is to increase adsorption, instead, Pristoupil clearly state that the washing step is preferred to obtain regular and reproducible results. Furthermore, Pristoupil, at page 113, 5th full paragraph, clearly teaches treating the membrane with neutral detergents to prevent non-specific adsorption of protein, so that they can be better separated during chromatography.

The argument that the method of Pristoupil does not result in a full separation of components based on some physical property is not persuasive since Pristoupil clearly state that "the principles valid for chromatography apply" (page 113, 5th full paragraph). The principles for chromatography teaches that substances least absorbed are least retarded and emerge the

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earliest while those more strongly absorbed emerge later. Clearly, this is a separation based on a physical property of the components (i.e. absorption). Furthermore, applicant argues that the separation of components into two zones, an adsorbed protein zone and a low molecular weight component zone, does not equate actual chromatographic separation of the components. This is not persuasive since at least two different components in a sample are separated, proteins being one and low molecular weight material being the other. The argument that this is not "specific" is not persuasive since nothing in the claims indicates anything other than simple separation of at least two different components, regardless of their types or characteristics.

Conclusion

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

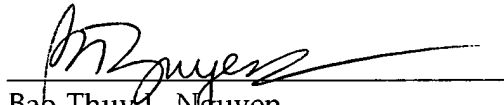
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy L. Nguyen
Primary Examiner
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January 25, 2003